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Education strategies are needed for women interested in genetic testing for inherited susceptibility to breast cancer, but who are at low to moderate risk based on family history. This project was designed to develop and test appropriate and effective education and counseling measures for women from different ethnic groups at low to moderate risk. The project includes the use of questionnaires, focus groups and a randomized controlled trial of education strategies to determine the most effective and an appropriate measures for use with low-to-moderate risk women from minority populations. Resulting strategies will be usefully applied in the large ethnically diverse populations of health maintenance organizations from which increasing numbers of women receive their health care. A survey of 9,877 ethnically diverse women ages 25-70 has been completed. Ethnic-specific focus groups comprised of African American, Latina, Asian and white women have been conducted. Design and implementation of appropriate educational interventions is ongoing.

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Catherine Schaefer 10/1/99

PI - Signature Date

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Introduction

To date, there has been little research on appropriate education strategies for women interested in testing for inherited susceptibility to breast cancer, but who are at low to moderate risk based on family history of cancer. Information about interest in and attitudes toward testing is especially scarce for women from minority populations and those of lower socioeconomic status.

These statements, which offered part of the rationale for conducting this study in the original grant proposal written in 1996, are still valid today. With some exceptions [1-3], even the recently-published studies funded under the auspices of the Human Genome Project did not include significant numbers of ethnic minorities and paid relatively little attention to education about cancer genetics in women at low risk of inherited susceptibility to cancer [4-9]. Population-based studies of the frequency of disease-related mutations in BRCA1 and BRCA2 have resulted in decreased estimates of the prevalence of disease-causing mutations in the general population [10-12], suggesting that fewer women are at high risk and more women have a low risk than was estimated shortly after the genes were first cloned [13]. Thus, the goal of developing appropriate educational materials for minorities and women with lower socioeconomic status, as well as women with low to moderate risk of inherited susceptibility to cancer remains an important one.

This project was designed to develop and test appropriate and effective education and counseling measures for women from different ethnic groups at low to moderate risk. The project includes the following elements: 1) A survey of the family history of breast and ovarian cancer, and of the prevalence of knowledge, attitudes, and intentions with regard to testing for inherited susceptibility to breast cancer among a racially and ethnically diverse sample of women served by Kaiser Permanente Medical Care Program (KPMCP) in northern California. 2) Focus groups will be used to further explore and define possible ethnic group differences in attitudes toward genetic testing. 3) A randomized controlled trial of 600 women with equal numbers of African American, Asian, Latina, and white women in each arm, will be conducted to test the effects of different educational materials on knowledge and understanding of cancer genetics, interest in genetic testing, and cancer screening behavior.

This annual report first describes our progress in accomplishing the first two aims of the study, and our progress in planning for implementation of the third aim.

Body

1. Survey of Family History, Screening Behavior and Attitudes Toward Testing in a Multiethnic Sample

In last year's report, we described our efforts to survey a stratified random sample of 16,795 women members of KPMCP in northern California. In preliminary work, the addresses of a random sample of 386,123 women members were geocoded (i.e., their

addresses were linked to the census block in which they lived), and the resulting codes were merged with the 1990 U.S. Census data which characterizes each census block (about 1000 individuals) according to the percentage of various ethnic groups living in the census block, as well as variables indicating the percentage with varying levels of education, percent in blue collar occupations, and other aspects of demographics and socioeconomic status. For sampling purposes, these data were used to substitute for unavailable individual-level data on ethnicity and socioeconomic status, in order to draw a sample that overrepresented women from African-American, Hispanic, and Asian backgrounds from diverse socioeconomic settings.

The mailed survey, included as Appendix A, inquired in some detail about the woman's family history of breast and ovarian cancer, her own cancer history, breast screening practices, knowledge about and attitudes toward genetic testing for inherited susceptibility to cancer, demographic factors (including ethnicity and education), as well as several questions concerning the woman's perceived susceptibility to breast cancer in comparison to a) other women her age, b) women with a different family history, and c) women from other ethnic groups.

A probability sampling scheme based on census block characteristics was devised to yield a sample that was 20% each African-American, Asian, and Hispanic, and 40% non-Hispanic white. The survey was mailed to 16,795 women, ages 25 to 70 years. A postcard reminder to complete the survey was sent to women after two weeks. Those not returning the questionnaire by four weeks were sent a second questionnaire, followed after two weeks by a second postcard requesting completion of the questionnaire. All returned questionnaires were coded and data were keyed in preparation for analyses.

2. Survey Results

The response rate for the mailed survey was rather low; 6,967 women (41%) returned completed questionnaires. In an effort to improve the overall response rate, we conducted telephone interviews with nonrespondents using a somewhat shortened version of the questionnaire (see Appendix B). Telephone interviews were completed with 2,910 nonrespondents (17%), resulting in a final sample of 9,877 women and a final response rate of 58%. The resulting sample was representative of the groups the sample was designed to study. As reported in the completed interviews/questionnaires, self-identification was 48% non-Hispanic white, 18% each African-American and Asian, and 16% Hispanic (Table 1, Appendix C) . Use of census block data to increase the representation of ethnic minorities in the sample was successful, but response rates were higher among women from census blocks with fewer residents with less than high school educations, and from blocks with less than 60% Asian or Hispanic residents.

a. Family History of Breast and Ovarian Cancer by Survey

The survey assessed family history and personal history of breast and ovarian cancer in a series of questions that included maternal and paternal grandmothers, aunts and cousins, mothers, sisters, daughters, and male blood relatives. Women were also asked about their own history of breast or ovarian cancer; 157 women (2.3%) had been diagnosed

with breast cancer; 73 women (1%) reported having been diagnosed with ovarian cancer. About 27% (1,839 women) reported having at least one relative who had been diagnosed with breast cancer; 12% (820 women) reported having at least one relative who had been diagnosed with ovarian cancer. Rates of breast cancer by age group, ethnicity, and education appeared consistent with the known epidemiology of breast cancer (Table 2, Appendix C). However, the very high percentages of women diagnosed with ovarian cancer or who reported relatives with ovarian cancer suggest that women may have confused ovarian cancer with other reproductive cancers. This supposition was supported by examination of rates of ovarian cancer by age group and educational level; rates reported at very young ages and for low levels of education appeared inconsistent with the epidemiology of ovarian cancer. We therefore considered the reports of ovarian cancer to be unreliable and did not include information on self or family history of ovarian cancer in our calculation of risk based on family history.

Based on reported personal and family history of breast cancer, we defined risk of inherited susceptibility to breast cancer as low, moderate or high according to the following criteria: Low risk included women with no personal history and no relatives with breast cancer. Moderate risk included women with a personal history of breast cancer and one relative with breast cancer, or women with no personal history and two relatives with breast cancer. High risk included women with a personal history and two or more relatives, plus women with no personal history and three or more relatives with breast cancer. Based on these categories, 58% of the survey respondents were at "low" risk of inherited susceptibility, 33% were at "moderate" risk, and 4% were at "high" risk.

Although statistically significant due to the large numbers of respondents, there was relatively little variability in risk attributable to family history by age group or education, but risk attributable to family history did differ by ethnicity (Table 3 and Figure 1, Appendix C). A significantly higher percentage of Asian women were low risk based on their family history, and significantly fewer were high risk. In comparison, a significantly lower percentage of non-Hispanic white women were at low risk based on family history, and a significantly higher percentage were moderate or high risk. The percentages of African-Americans and Hispanics at low and high risk were similar and intermediate between that of Asians and non-Hispanic whites.

b. Perceived Risk of Breast Cancer

Overall, 47% of respondents said they "never" or "rarely" think about getting breast cancer, and 13% worry "a great deal". Asked to compare themselves to other women the same age, 46% perceived their own risk as lower, 40% as similar, and 14% as higher or much higher compared with same-aged women. Survey respondents perceived the risk of breast cancer to women with a family history similar to their own to be "low" (58%), "some" (35%) or "high" (7%) - strikingly similar to the percentages of women who reported family histories that were categorized as "low", "moderate" or "high" risk. We have not yet examined the extent of correlation between respondents' perceptions of risk associated with family history and their category of risk based on the family history that they reported.

Asked to compare the risk of breast cancer in women with their ethnic background to women of other backgrounds, women perceived the risk of breast cancer differently depending on ethnicity. The majority of Asian women perceived the risk of breast cancer in women with their ethnic background to be lower when compared to other women; African American women perceived the risk to African American women to be significantly higher when compared to all other women. These differences are illustrated in Figure 2 in Appendix C.

c. Knowledge of and Interest In Genetic Testing

In response to questions about knowledge of genetic testing, 75% of survey respondents had heard "nothing" or "very little" about genetic testing for inherited susceptibility to breast cancer, 22% had heard "a fair amount", and 3% had heard or read "a lot" about genetic testing. Despite knowing little about the test, 65% of respondents were interested in receiving genetic testing for breast cancer; 46% remained interested in testing even if breast cancer could not be prevented. High risk based on family history of breast cancer was associated with at least some knowledge of genetic testing, and there was a graded association between risk based on family history and interest in being tested (Figure 3, Appendix C), with interest in testing increasing as extent of family history of breast cancer increased.

We performed a multivariate logistic regression analysis to examine the joint and independent association of various factors with interest in genetic testing (Table 4, Appendix C). This analysis showed that younger age, Asian race, and knowledge of genetic testing were significantly and negatively associated with interest in testing, while more education, a positive family history of breast cancer, and a higher perceived risk of breast cancer compared to other women the same age, were significantly and positively associated with interest in genetic testing.

At present, we are completing the analyses of the survey data after integrating the data from the telephone interviews with nonrespondents. Tables and Figures presented in this report were based on the mailed survey only, and will be revised to incorporate the results of the newer analyses. We are preparing a manuscript for publication based on the complete survey results. To our knowledge, this publication will be one of the first to report information about family history of breast cancer in Asian and Hispanic women, and to examine relationships among family history, perceived risk of breast cancer, and interest in genetic testing in a multiethnic sample.

3. Ethnic- Specific Focus Groups

We have conducted eight ethnic-specific focus groups - two groups each for women who self-identified as African American, Asian, Hispanic, or white - to obtain further information to inform the design of the educational materials and the clinical trial that will test the effectiveness of different strategies. Each focus group was composed of 4 to 6 women who were selected from those who returned the mailed survey. Each focus

group was led by an experienced focus group leader who was also a woman of the same ethnic background as the participants in the group. The groups were videotaped and audiotaped. Meetings lasted about two hours and were held in the evening. Participants were provided sandwiches and drinks and were paid a nominal fee for their time.

A single standard agenda was followed by all groups (Appendix D). The agenda covered four main areas: a) women's knowledge and opinions about breast cancer in general; b) knowledge and opinions about family history and inherited susceptibility to breast cancer; c) pros and cons of genetic testing for inherited susceptibility to breast cancer and implications of positive or negative test results; d) opinions about how genetic testing should be handled by Kaiser Permanente and how best to inform women about issues such as genetic testing.

Our intent in conducting these focus groups was not to conduct a formal content analysis of the results, but to use the results to "fine-tune" educational materials for sensitivity and relevance to the concerns of different groups. However, Dr. Beth Newman, a consultant to the project since its inception, recently informed us that she would like to supervise one of her graduate students in performing a formal content analysis of the focus group materials. At present, we are preparing the materials for transfer to Dr. Newman, who will arrrange to have the audiotapes transcribed and analyzed.

For our own purposes, we have repeatedly reviewed the taped focus group dialogues that occasioned the most discussion and differences of opinion, and compared these pieces across the groups. With the exception of a few women who had personal experience with family members who had had breast cancer, most women did not appear overly concerned about their own risk of developing breast cancer. It was apparent, however, that in nearly every group women felt as if they should be doing something to reduce their own risk of breast cancer, and mentioned factors such as reducing the fat in their diets and getting more exercise.

The most striking feature common to all focus groups was the overall lack of knowledge about breast cancer and factors associated with increased risk of breast cancer. Environmental risk factors were identified by all focus groups as being important, although different factors were named by each group. Factors included drinking water, pesticides, chemical exposure, stress and emotional distress, radiation, exposure to light, cheap bras, and chemicals in meat and fish. None of the women in the groups had any conception of a woman's lifetime risk of breast cancer, or increases in risk of breast cancer with increasing age. Women in the groups struggled with the concepts of increased risk due to an inherited susceptibility that is low in prevalence, and an average or background risk that reflects the high prevalence of breast cancer.

Most women thought that a genetic test for inherited susceptibility to breast cancer was something they might be interested in taking, and all groups thought the primary utility of a genetic test would be to motivate them to make changes in lifestyle to prevent breast cancer if they were found to be at risk. Women said they would be interested in taking a

genetic test for "peace of mind". Most women agreed that, although family members should be informed of genetic testing results, the choice to undergo the test should be an individual one. Few women expressed any concern about issues of confidentiality and potential consequences of testing for employability or insurability.

Each group expressed surprise and rejection of the idea of prophylactic mastectomy as a means of preventing breast cancer in women with high risk, although there did appear to be some differences in the reasoning behind the rejection of the concept. Some women felt that there were too many uncertainties associated with predictive testing and the likelihood of getting breast cancer to warrant such a drastic surgery. Other women expressed concern about physical appearance after surgery, and the responses of their partners/spouses. Older women were somewhat more accepting, with some expressing the opinion that their breasts had served their purpose which was to nurse their children.

Prior to receiving the results of Dr. Newman's formal qualitative analysis of the focus groups, we will continue with analysis of selected sections of the materials for the purposes of refining the educational interventions for the trial.

4. Development of Educational Interventions and Planning for a Randomized Control Trial

At the time the proposal for this research was being prepared, it was expected that there might be a large number of Kaiser members who would be interested in learning more about genetic testing for inherited susceptibility to breast cancer, regardless of their family history or likelihood of having an inherited mutation. One consequence of this expectation was the development and publication by Kaiser Permanente of a referral guideline for genetic counseling concerning inherited susceptibility to breast cancer. It was anticipated that many women would be interested in learning more about genetic testing, but that the number of women who would be appropriate for referral for counseling (and the counseling resources to accommodate them) would be small relative to the number of women expressing interest in the test. As a result of this perceived need, geneticists and genetic counselors developed a 2-hour class to which interested Kaiser members are referred. The class covers much of the material that would be in a one-on-one session with a genetic counselor, but of course includes no personalized risk information. Classes are offered at all four Genetics Departments in Northern California.

Each class is intended to provide enough background for participants to be able to make an informed decision about whether individual genetic counseling with the possibility of subsequent testing is appropriate. Each class includes an educational component about the science behind BRCA testing, including a discussion of chromosomes, genes, autosomal dominant inheritance, the tumor suppressor model of inherited susceptibility, and the difference between "cancer" and a "susceptibility to cancer". The process of developing a pedigree, reviewing personal and family history of cancer, and assessing genetic risk is explained. The test itself is explained, including both how the test is done, as well as the associated possible positive, negative and ambiguous results. The possible

medical impact of both a positive and a negative test are explained. The complex ethical legal and social issues of testing are explained, including the possible impact on families and relationships, employment and insurability. The classes all include the same information, and are taught by a team of two genetic counselors or a medical geneticist and a genetic counselor.

Since part of the rationale for our study is the development of educational materials that can be used in an HMO setting, we have decided to adopt the materials and class structure developed by the Regional Genetics Departments as one of the interventions for the randomized control trial, since it is presently being used. The intervention to which it will be compared is still under development, although we have decided on most of the central elements. As a consequence of our findings from the focus groups, the second intervention will include a broader scope of information than the focus on inherited susceptibility and genetic testing; we will try to educate women about breast cancer in such a way that the genetic risk and genetic testing will be placed in a broader context of other risk factors and rapidly developing findings about prophylactic treatments such as tamoxifen and raloxifene. The participants in the focus groups clearly expressed a strong interest in the integration of information about susceptibility testing for breast cancer with other aspects of breast care. The second intervention will also be administered in a class or group setting, in order to minimize differences due to the medium of the message. We plan to have completed design of the second intervention and pilot testing of the materials by the end of November 1999.

For purposes of conducting the trial, we will recruit women from the respondents to our survey, and assign them at random to one of the two interventions. A series of dates and times for each of the two "classes" will be offered to participants to accommodate their schedules. A total of 600 women will be enrolled, with 50% assigned to each intervention. Women will be randomized within ethnicity, so as to insure equal representation of each of the four major ethnic groups under study in each arm of the trial; i.e., there will be 75 women from each ethnic group in each arm of the trial. Group/class sizes will be kept relatively small, necessitating the scheduling of a large number of groups. All of the groups will have been conducted by March, 2000.

We are somewhat behind our intended time line for accomplishment of these tasks. However, we are on target with respect to expenditures, and anticipate that we will be able to accomplish all of the study's aims within the original study budget.

Key Research Accomplishments:

1. Completion of survey:

- Preliminary results are based on 9,877 ethnically diverse women (48% non-Hispanic white, 18% each African American and Asian, 16% Hispanic) respondents (58% response rate) to a survey conducted in 1998 on family history of breast and ovarian cancer, knowledge of breast cancer and genetic testing, and perception of risk.

- Family history: 58% of survey respondents were at "low" risk of inherited susceptibility (no personal or family history), 33% were at "moderate" risk (personal history and at least one additional relative, or 2 or more relatives), 4% were at "high" risk (personal history and 2 relatives, or 3 or more relatives with breast cancer). 2.3% of respondents had a personal history of breast cancer, 1% had a personal history of ovarian cancer. The percentages of women reporting a family history of ovarian cancer were too high to be reliable.

- Perception of vulnerability: Survey respondents perceived the risk of breast cancer to women with a family history similar to their own to be "low" (58%), "some" (35%) or "high" (7%) - strikingly similar to the percentages of women reporting "low", "moderate" and "high" risk family histories. Women perceived the risk of breast cancer among women from their own ethnic background differently depending on ethnicity. Asian women perceived the risk of breast cancer to Asian women to be lower when compared to women in general; African American women perceived the risk to African American women to be higher when compared to women in general. Note that this is the first relatively large survey of family history, knowledge and attitudes in Asian and Hispanic women.

- Genetic testing: 75% of survey respondents had heard "nothing" or "very little" about genetic testing for breast cancer; 22% had heard "a fair amount" and 3% had heard or read "a lot" about genetic testing. 65% of respondents were interested in receiving genetic testing for breast cancer; 46% remained interested in testing even if breast cancer could not be prevented.

- Multivariate analysis: In multivariate analyses of factors predicting interest in genetic testing, younger age, more education and positive family history of breast cancer were significantly and positively associated with interest in genetic testing; Asian race and knowledge of genetic testing were significantly and negatively associated with interest in testing.

2. Completion of eight ethnic-specific focus groups.

Impressions from the focus groups are described in the body of this report. A formal analysis is ongoing.

3. Planning for randomized control trial is close to completion.

Reportable Outcomes:

Results of the survey were presented at a research conference in March 1999:
Catherine Schaefer, Sarah Rowell, Robert A. Hiatt, Beth Newman, JoAnn Bergoffen.
Educational Options For Women At Low Risk Of Inherited Breast Cancer In A Multi-Ethnic Health Plan, HMO Research Network Conference, Kahuku, HI, March 4-6, 1999.

Conclusions:
We would prefer not to state conclusions at this time; we view the results to date as preliminary.

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APPENDIX A

KAISER PERMANENTE

UNDERSTANDING BREAST CANCER AND FAMILIES

CONFIDENTIAL

The purpose of this questionnaire is to help us understand how women think about breast cancer, and how their experiences affect those thoughts. There are no right or wrong answers to these questions; please just report what best describes your situation.

Your responses to these questions will be kept completely confidential.

Before starting this questionnaire, please check the information on the label above. If there are errors, please cross out the wrong information on the label and write in the correct information.

1. **What is your date of birth?** _____/_____/_____ (MM / DD / YY)

2. **Compared to other women your age, would you say your health is:**
   1☐ Poor 2☐ Fair 3☐ Good 4☐ Very good 5☐ Excellent

These next questions are about breast care, and about breast conditions you may have had.

3. **During the past two years, how many times did a physician or other health care professional conduct a breast exam on you?**
   1☐ Never 2☐ Once 3☐ Twice 4☐ Three or more times 5☐ Don't know

4. **During the past two years, did you do a breast exam on yourself?** (That is, have you ever felt your own breasts the way a doctor or nurse does to look for lumps or changes?)
   1☐ Yes →
   2☐ No
   3☐ Don't know

   How often did you conduct a breast exam on yourself in the last two years?
   1☐ Less than once a year
   2☐ About once or twice a year
   3☐ Every 2 to 3 months
   4☐ About once a month
   5☐ More often than once a month

5. **A mammogram is an x-ray of the breast taken by a machine that presses against the breasts while the picture is taken. Have you ever had one?**
   1☐ Yes → →
   2☐ No → *Skip to question 7*
   3☐ Don't know

   About how long has it been since you had your last mammogram?
   1☐ 1 year ago or less
   2☐ Between 1-2 years ago
   3☐ More than 2 years ago

6. **Women have mammograms either because of a problem, like a lump, or for a check-up. What was the reason for your last mammogram?**
   1☐ A problem (such as a lump, pain or discharge) 2☐ A check-up 3☐ Don't know

7. **Have you ever had a breast biopsy?** *(Please include surgical and needle biopsies as well as needle aspirations.)*
   1☐ Yes →
   2☐ No
   3☐ Don't know

   How many biopsies have you had? _____ _____

The following questions are about your blood relatives (that is <u>not</u> including family members who are adopted or married into the family) and any breast or ovarian cancer they may have had. Please answer all the questions, even if no one in your family has ever been diagnosed with breast or ovarian cancer. Please include information about all of your relatives, even if they are deceased.

8. Has your mother ever been diagnosed with breast or ovarian cancer?

1☐ Yes → a. Did she have breast cancer, ovarian cancer or both? 1☐ Breast cancer 2☐ Ovarian cancer 3☐ Both
b. How old was she when she was first diagnosed? _____ years old

2☐ No

3☐ Don't know

9. Has your maternal grandmother (mother's mother) ever been diagnosed with breast or ovarian cancer?

1☐ Yes → a. Did she have breast cancer, ovarian cancer or both? 1☐ Breast cancer 2☐ Ovarian cancer 3☐ Both
b. How old was she when she was first diagnosed? _____ years old

2☐ No

3☐ Don't know

10. Has your paternal grandmother (father's mother) ever been diagnosed with breast or ovarian cancer?

1☐ Yes → a. Did she have breast cancer, ovarian cancer or both? 1☐ Breast cancer 2☐ Ovarian cancer 3☐ Both
b. How old was she when she was first diagnosed? _____ years old

2☐ No

3☐ Don't know

11. a. How many sisters and half-sisters do you have? ____ ____ sisters ____ ____ half-sisters
If you have no sisters or half-sisters, please skip to question 12.

b. Have any of your sisters or half-sisters ever been diagnosed with breast cancer?

1☐ Yes → i. How many of your sisters? ..... ____ ____
ii. How many of your half-sisters? ..... ____ ____
iii. How many of your sisters were diagnosed before they were 50 years old? ..... ____ ____
iv. How many of your half-sisters were diagnosed before they were 50 years old? ..... ____ ____

2☐ No

3☐ Don't know

c. Have any of your sisters or half-sisters ever been diagnosed with ovarian cancer?

1☐ Yes → i. How many of your sisters? ..... ____ ____
ii. How many of your half-sisters? ..... ____ ____

2☐ No

3☐ Don't know

12. a. How many daughters do you have? ____ ____ *If none, skip to Question 13*

b. Have any of your daughters ever been diagnosed with breast cancer ?

1☐ Yes → i. How many of your daughters? ..... ____ ____
ii. How many of your daughters were diagnosed before they were 50 years old? ..... ____ ____

2☐ No

3☐ Don't know

c. Have any of your daughters ever been diagnosed with ovarian cancer?

1☐ Yes → How many of your daughters? ..... ____ ____

2☐ No

3☐ Don't know

13. Have any of your maternal aunts (your mother's sisters) ever been diagnosed with breast cancer?

1☐ Yes →
2☐ No
3☐ I have no maternal aunts
4☐ Don't know

i. How many of your maternal aunts? ..... ___ ___
ii. How many of your maternal aunts were diagnosed before they were 50 years old? ..... ___ ___

14. Have any of your female cousins on your mother's side of the family ever been diagnosed with breast cancer?

1☐ Yes →
2☐ No
3☐ I have no female cousins on this side
4☐ Don't know

i. How many of your cousins ? ..... ___ ___
ii. How many of your cousins were diagnosed before they were 50 years old? ..... ___ ___

15. Have any of your paternal aunts (your father's sisters) ever been diagnosed with breast cancer?

1☐ Yes →
2☐ No
3☐ I have no paternal aunts
4☐ Don't know

i. How many of your paternal aunts? ..... ___ ___
ii. How many of your paternal aunts were diagnosed before they were 50 years old? ..... ___ ___

16. Have any of your female cousins on your father's side of the family ever been diagnosed with breast cancer?

1☐ Yes → →
2☐ No
3☐ I have no female cousins on this side
4☐ Don't know

i. How many of your cousins? ..... ___ ___
ii. How many of your cousins were diagnosed before they were 50 years old? ..... ___ ___

17. Have any of your aunts or female cousins ever been diagnosed with ovarian cancer?
(Please include your paternal and maternal aunts, and female cousins on both sides of the family.)

1☐ Yes →
2☐ No
3☐ I have no aunts or female cousins
4☐ Don't know

How many of your aunts and female cousins ? ..... ___ ___

18. Do you have any male relatives who have ever been diagnosed with breast cancer

1☐ Yes →
2☐ No
3☐ Don't know

Which relatives?
_____

19. Have any close friends been diagnosed with breast or ovarian cancer?

1☐ No 2☐ Yes, breast cancer 3☐ Yes, ovarian cancer 4☐ Yes, both 5☐ Don't know

20. Have you ever been told by a doctor that you had breast or ovarian cancer?

1☐ Yes →
2☐ No
3☐ Don't know

a. Were you told you had breast cancer, ovarian cancer or both?
1☐ Breast cancer 2☐ Ovarian cancer 3☐ Both
b. How old were you when you were first diagnosed? _____ years old

↓
Skip to question 27

The next few questions ask for your thoughts and opinions..

21. How frequently do you think about getting breast cancer?

1☐ Never 2☐ Rarely 3☐ Sometimes 4☐ Often 5☐ All the time

22. In your opinion, compared to other women your age, what are your chances of getting breast cancer?

1☐ Much lower 2☐ A little lower 3☐ About the same 4☐ A little higher 5☐ Much higher

23. In your opinion, what are the chances that women with your family history of breast cancer will develop breast cancer?

1☐ Very low chance 2☐ Low chance 3☐ Some chance 4☐ High chance 5☐ Very high chance

24. In your opinion, what are the chances that women of your racial or ethnic background will get breast cancer, compared to women in general?

1☐ Much lower chance 2☐ A little lower chance 3☐ About the same 4☐ A little higher chance 5☐ Much higher chance

25. Compared to other health problems or diseases, how much do you worry about breast cancer?

1☐ Not at all 2☐ A little bit 3☐ Some 4☐ Quite a bit 5☐ A great deal

26. How do you react to information about breast cancer in the media (such as radio, TV or magazines)?

1☐ Seek out programs or articles on breast cancer
2☐ Listen, watch or read if you happen to come across them
3☐ Feel you should listen, watch or read them
4☐ Ignore programs or articles
5☐ Avoid programs or articles

27. Have you ever spoken with a health care professional about your family history of breast cancer?

1☐ Yes → Who did you speak with? (*Check all that apply.*)
- 1☐ Primary care provider
- 2☐ Nurse practitioner
- 3☐ Geneticist/genetic counselor
- 4☐ Other (*Please specify*) _____

2☐ No

3☐ Don't know

28. How do you feel about your knowledge of breast cancer right now?

1☐ I need a lot more information
2☐ I need a little more information
3☐ I have enough information
4☐ I have too much information

The next questions ask about some recent breast cancer research you may have heard about.

29. How much have you read or heard about genetic testing for breast cancer?

1☐ Almost nothing 2☐ Relatively little 3☐ A fair amount 4☐ A lot

30. Genetic testing for inherited risk of breast cancer is now possible for some people. If a blood test could tell you how likely it is that you will get breast cancer (again), would you be interested in taking that test?

1☐ Yes → If the blood test could tell you about your chances of getting breast cancer (again), but if you could not prevent the disease, would you still be interested in taking the test?
1☐ Yes 2☐ No 3☐ Don't know

2☐ No

3☐ Don't know

These final questions ask for some background information about you.

31. What is your current marital status?

1☐ Single, never married
2☐ Married or living as married
3☐ Separated or divorced
4☐ Widowed

32. What is your race/ethnicity? *(Check all that apply)*

1☐ White
2☐ Black/African-American
3☐ Hispanic/ Latina
4☐ Chinese
5☐ Japanese
6☐ Other Asian
7☐ Pacific Islander
8☐ Native American
9☐ Other *(Specify* _____*)*

33. Do you prefer to read or speak a language other than English?

1☐ Yes →
2☐ No
3☐ Don't know

What language do you prefer?
1☐ Spanish
2☐ Cantonese
3☐ Tagalog
4☐ Other (*Please specify* _____*)*

34. What is your religious background?

1☐ Buddist
2☐ **Catholic**
3☐ **Hindu**
4☐ **Jewish**
5☐ Protestant
6☐ **Muslim**
7☐ **None**
8☐ Other (*Please specify* _____*)*

35. Please indicate the highest grade that you completed in school. *(Circle one number)*

K 1 2 3 4 5 6 7 8	9 10 11 12	13 14 15 16	17+
GRADE SCHOOL	HIGH SCHOOL	COLLEGE OR TECHNICAL SCHOOL	GRADUATE OR PROFESSIONAL SCHOOL

36. This questionnaire is part of a study of what women think about breast cancer and testing for inherited risk. We will be inviting some of the women who have completed this questionnaire to take part in other parts of the study. May we contact you to tell you more about the study?

1☐ Yes, please
2☐ No, thank you

Many thanks for taking the time to complete this questionnaire!

APPENDIX B

KAISER BREAST CANCER SURVEY
March 18, 1998

PURPOSE

The purpose of this survey is to help us understand how women think about breast cancer, and how their experiences affect those thoughts. There are no right or wrong answers to these questions; please just report what best describes your situation. Your responses to these questions will be kept completely confidential. They will not become a part of your medical record. Your participation or refusal will not alter your relationship with Kaiser Permanente in any way. May I continue?

1. Yes
2. No (END INTERVIEW)

PREFER

1. Do you prefer to read or speak a language other than English?

1. Yes
2. No (GO TO BIRTHDAY)
7. DK (GO TO BIRTHDAY)
9. RF (GO TO BIRTHDAY)

LANGUAGE

1a. Which language do you prefer to speak?

1. Spanish
2. Cantonese
3. Mandarin
4. Tagalog
5. Japanese
6. Other (specify)

REGRET

1b. I am sorry we have not translated these questions into (preferred language). Would you be willing to answer these questions in English?

1. Yes
2. No (GO TO CLOSING)

BIRTHDAY

2. What is your date of birth? ___/___/___
mm dd yy

7. DK
9. RF

GENHLTH

3. Compared to other women your age, would you say your health is:

1. Poor
2. Fair
3. Good
4. Very Good, or
5. Excellent
7. DK
9. RF

The next few questions are related to breast cancer and ask for your thoughts and opinions. Remember there are no right or wrong answers; we are interested in your opinion.

FREQ_GET

4. How frequently do you think about getting breast cancer?

1. Never
2. Rarely
3. Sometimes
4. Often
5. All the time
7. DK
9. RF

OTHRHLTH

5. Compared to other health problems or diseases, how much do you worry about getting breast cancer?

1. Not at all
2 A little bit
3. Some
4. Quite a bit
5. A great deal
7. DK
9. RF

OPINION

6. In your opinion, is there too much, too little or just the right amount of attention to breast cancer in the media, such as TV, magazines or newspapers? Would you say...

1. There is too much attention
2. The amount of attention is about right
3. There is too little attention
7. DK
9. RF

The following questions are about breast and ovarian cancer in members of your family. Please include information about all of your blood relatives, even if they are no longer living, but do not include family members who are adopted or married into the family.

HAVERELS

7. Do you have any relatives who have ever been diagnosed with breast cancer?

1. Yes
2. No (GO TO ANYRELS)
7. DK (GO TO ANYRELS)
9. RF (GO TO ANYRELS)

RELWHO

7a. Which relatives? Read and select all that apply.

1. Mother
2. Sisters
3. Half-sisters
4. Paternal Aunts
5. Maternal Aunts
6. Maternal Grandmother
7. Paternal Grandmother
8. Cousins
9. Other

ANYRELS

8. Do you have any relatives who have ever been diagnosed with ovarian cancer?

1. Yes
2. No (GO TO HLTHPRO)
7. DK (GO TO HLTHPRO)
9. RF (GO TO HLTHPRO)

WHATRELS

8a. Which relatives? Read and select all that apply.

1. Mother
2. Sisters
3. Half-sisters
4. Paternal Aunts
5. Maternal Aunts
6. Maternal Grandmother
7. Paternal Grandmother
8. Cousins
9. Other
77. DK
99. RF

Ask if either HAVERELS = 1 or ANYRELS = 1, otherwise go to FRIENDS

HLTHPRO

9. Have you ever spoken with a health care professional about your family history of breast or ovarian cancer?

1. Yes
2. No (GO TO FRIENDS)
7. DK (GO TO FRIENDS)
9. RF (GO TO FRIENDS)

WHOPRO

9a. Who did you speak with?

1. Primary Care Provider
2. Geneticist/Genetic Counselor
3. Nurse Practitioner
4. Obstetrician/Gynecologist
5. Other (specify)
7. DK
9. RF

FRIENDS

10. Have any of your close friends been diagnosed with breast or ovarian cancer? (If yes: Probe for which type.)

1. No
2. Yes, breast cancer
3. Yes, ovarian cancer
4. Yes, both
5. Other
7. DK
9. RF

Scientists have recently discovered that some cases of breast cancer are caused by genes that are passed from one generation to the next. These genes may increase the chance that a woman will develop breast or ovarian cancer sometime in her life. Genetic testing using a blood sample is now available in some places.

GENTEST

11. How much have you read or heard about genetic testing for breast cancer?

1. Nothing\Almost nothing
2. Relatively little
3. A fair amount
4. A lot
7. DK
9. RF

LEARNTST

12. If you wanted to learn more about genetic testing for breast cancer, which of the following ways would you prefer to learn more? Read and mark all that apply.

1. Brochure or pamphlet you could read
2. One-on-one talk with a health care professional
3. A videotape you could take home
4. A group discussion with a health care professional
5. A family visit with a health care professional
→ 7. Don't want to know more
77. DK
99. RF

BLOODTST

13. If a blood test could tell you if you carried a gene that affected your chances of getting breast cancer, would you be interested in taking that test?

1. Yes
2. No (GO TO DOTALK)
7. DK (GO TO DOTALK)
9. RF (GO TO DOTALK)

CHANCES

13a. If the blood test could tell you about your chances of getting breast cancer, but if you could not prevent it, would you still be interested in taking the test?

1. Yes
2. No
7. DK
9. RF

DOTALK

14. Besides talking to their doctors, women may talk to other people about their health care. Do you talk to anyone, besides your doctor, about your health?

1. Yes
2. No (GO TO HAVEXAM)
7. DK (GO TO HAVEXAM)
9. RF (GO TO HAVEXAM)

WHOTALK

14a. From the following list, who do you usually talk to when you are making decisions about your health? Enter all that apply

1. Your friends
2. Your sisters or brothers
3. Your children
4. Your husband or partner
5. A religious or spiritual advisor
6. Your parents
7. A counselor or therapist
8. Anyone else?
77. DK
99. RF

These next questions ask about health practices:

HAVEXAM

15. During the past two years, how many times did a physician or other health care professional conduct a breast exam on you?

1. Never
2. Once
3. Twice
4. Three or more times
5. Didn't see a physician
7. DK
9. RF

DOEXAM

16. **During the past two years, did you do a breast exam on yourself? (That is, have you ever felt your own breast the way a doctor or nurse does to look for lumps or changes?)**

(Interviewer: If respondent had both breasts removed, enter NA)

1. Yes
2. No (GO TO MAMMO)
7. DK (GO TO MAMMO)
9. RF (GO TO MAMMO)
8. NA (Go to MAMMO)

OFTENBE

16a. How often did you conduct a breast exam on yourself in the last two years? Would you say...

1. Less than once a year
2. A few times a year
3. About once a month
4. More often than once a month
7. DK
9. RF

MAMMO

17. A mammogram is an x-ray of the breast taken by a machine that presses against the breast while the picture is taken. Have you ever had one?

1. Yes
2. No (GO TO BIOPSY)
7. DK (GO TO BIOPSY)
9. RF (GO TO BIOPSY)

HADMAM

17a. About how long has it been since you had your last mammogram?

1. 1 year ago or less
2. Between 1-2 years ago
3. More than 2 years ago
7. DK
9. RF

WHYMAM

18. Women have mammograms either because of a problem, like a lump, or for a checkup. What was the reason for your last mammogram? Would you say it was for...

1. A problem (such as a lump, pain or discharge) or
2. A check-up
7. DK
9. RF

BIOPSY

19. Have you ever had a breast biopsy? (Please include surgical and needle biopsies as well as needle aspirations.)

1. Yes
2. No (GO TO DR_TELL)
7. DK (GO TO DR_TELL)
9. RF (GO TO DR_TELL)

HOWMANY

19a. How many biopsies have you had? _____

7. DK
9. RF

DR_TELL

20. Have you ever been told by a doctor that you had breast or ovarian cancer?

1. Yes
2. No (GO TO MARITAL)
7. DK (GO TO MARITAL)
9. RF (GO TO MARITAL)

WHATTOLD

20a. Were you told that you had breast cancer, ovarian cancer, or both?

1. Breast cancer
2. Ovarian cancer
3. Both
7. DK (GO TO MARITAL)
9. RF (GO TO MARITAL)

AGE

20b. How old were you when you were first diagnosed? Enter age first told had cancer.

_____ ____YRS

7. DK
9. RF

These last few questions ask for a little background information about you.

MARITAL

21. What is your current marital status?

1. Single, never married
2. Married or living as married
3. Separated or divorced
4. Widowed
7. DK
9. RF

RACE

22. What is your race/ethnicity? Enter all that apply.

1. White
2. Black/African-American
3. Hispanic/Latina
4. Chinese
5. Japanese
6. Other Asian
7. Pacific Islander
8. Native American
9. Other (specify____RACETXT)
77. DK
99. RF

EDUCA

23. What is the highest grade that you completed in school?

1. Did not go to school
2. Grade school (K-8)
3. High school-did not graduate (9-11)
4. High school graduate (12)
5. Some college or technical school
6. College graduate
7. Graduate or professional school
77. DK
99. RF

CONTACT

24. This survey is part of a study to determine what women think about breast cancer and testing for inherited risk. We will be inviting some of the women who have completed this survey to take part in other aspects of the study. May we contact you to tell you more about the study?

1. Yes
2. No

Many thanks for taking the time to complete this survey!

APPENDIX C

Table 1. Selected Demographic Characteristics of Women Responding to Mailed Survey on Family History of Breast and Ovarian Cancer, Knowledge and Attitudes Toward Genetic Testing for Inherited Susceptibility, northern California, 1998, (n = 6,967)[a]

Demographic Characteristics	Percent of Sample
Age:	
25-34	18%
35-44	26%
45-54	25%
55-71	31%
Ethnicity:	
Asian	18%
Black	18%
Hispanic	16%
Non-Hispanic White	48%
Education:	
Grade school	4%
High school	25%
Some college	49%
College grad./+	22%
Prefer to speak language other than English:	
Yes	16%
No	84%
Don't Know	0.5%

[a] Table percentages based on mailed survey data only; addition of telephone survey data is in progress.

Table 2. Reported History of Diagnosis with Breast or Ovarian Cancer by Age, Ethnicity, and Education

		Age Group in Years			
Percent w/ History of	N	25-34	35-44	45-54	55-71
Breast Cancer	157	0%	0.87%	2.7%	4.4%
Ovarian Cancer	63	0.4%	0.7%	0.7%	1.5%

		Ethnicity			
	N	Asian	Black	Hisp.	White
Breast Cancer	157	1.7%	2.5%	0.95%	2.8%
Ovarian Cancer	63	0.4%	1.4%	1.1%	0.8%

		Education			
	N	Gr. Schl.	High Schl.	Some Coll.	Coll. Grad.
Breast Cancer	154	1.5%	1.8%	2.4%	2.6%
Ovarian Cancer	62	1.5%	1.3%	0.8%	0.5%

Table 3. Risk Attributable to Family History of Breast Cancer by Age Group, Ethnicity, and Education

Age Group in Years

Family History of Breast Cancer	N	25-34	35-44	45-54	55-71	*p**
Low	4260	68%	63%	59%	62%	.001
Moderate	2237	29%	32%	36%	34%	
High	308	3%	4%	5%	5%	

Ethnicity

Family History of Breast Cancer	N	Asian	Black	Hisp.	White	*p**
Low	4074	79%	60%	66%	56%	.001
Moderate	2160	19%	36%	31%	38%	
High	294	2%	4%	3%	6%	

Education

Family History of Breast Cancer	N	Gr. Schl.	High Schl.	Some Coll.	Coll. Grad.	*p**
Low	4221	74%	65%	61%	61%	.001
Moderate	2222	24%	31%	34%	34%	
High	307	2%	4%	5%	5%	

* probability value for chi square test of association

Table 4. Logistic Regression Analysis of Factors Associated with Interest in Genetic Testing

Variable	Odds Ratio
Age in years	0.97
Ethnicity [White referent]	
Asian	0.64
Hispanic	1.01
African-American	0.95
Education	1.12
Family Hx of Breast Cancer (L,M,H)l	1.34
Perceived Chances of Getting Breast Cancer	1.34
Knowledge of Genetic Testing	0.89

Figure 1. Risk of Inherited Susceptibility to Breast Cancer Based on Family History by Ethnicity

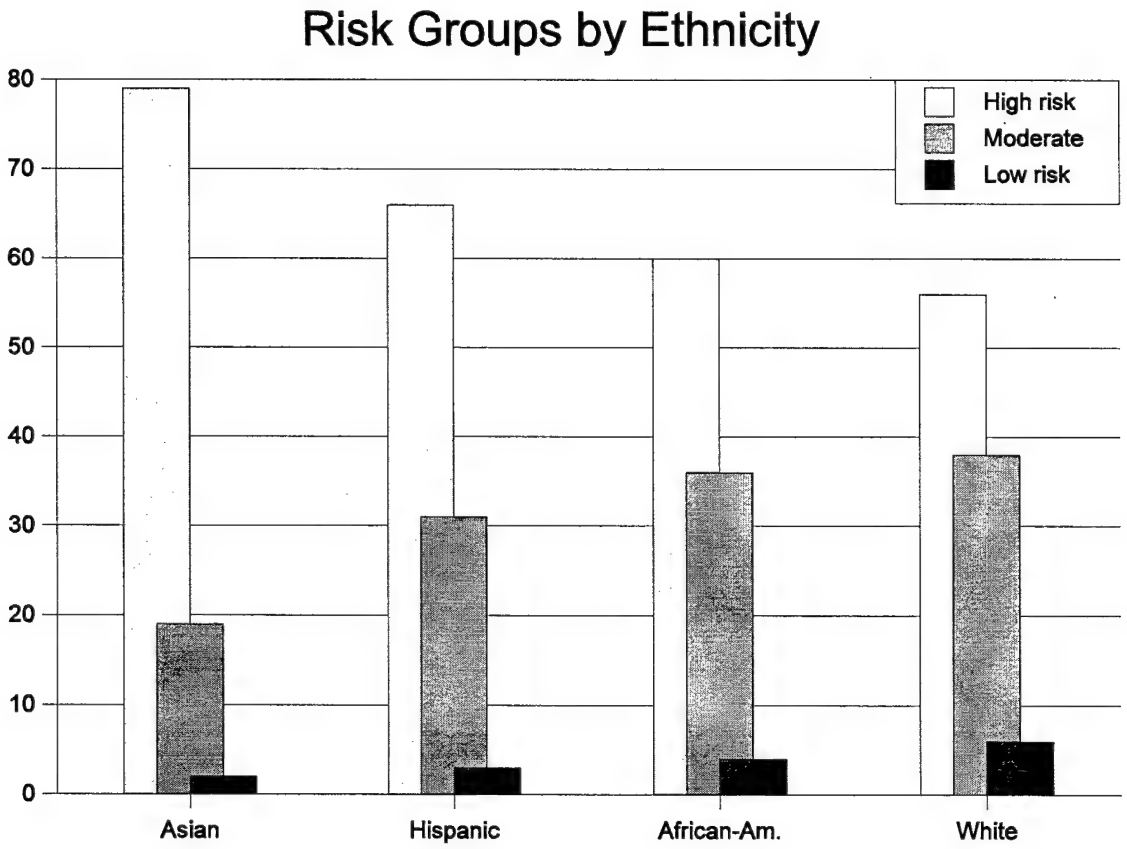


Figure 2. Women's Perceived Susceptibility to Breast Cancer in their Ethnic Group Compared to All Other Groups

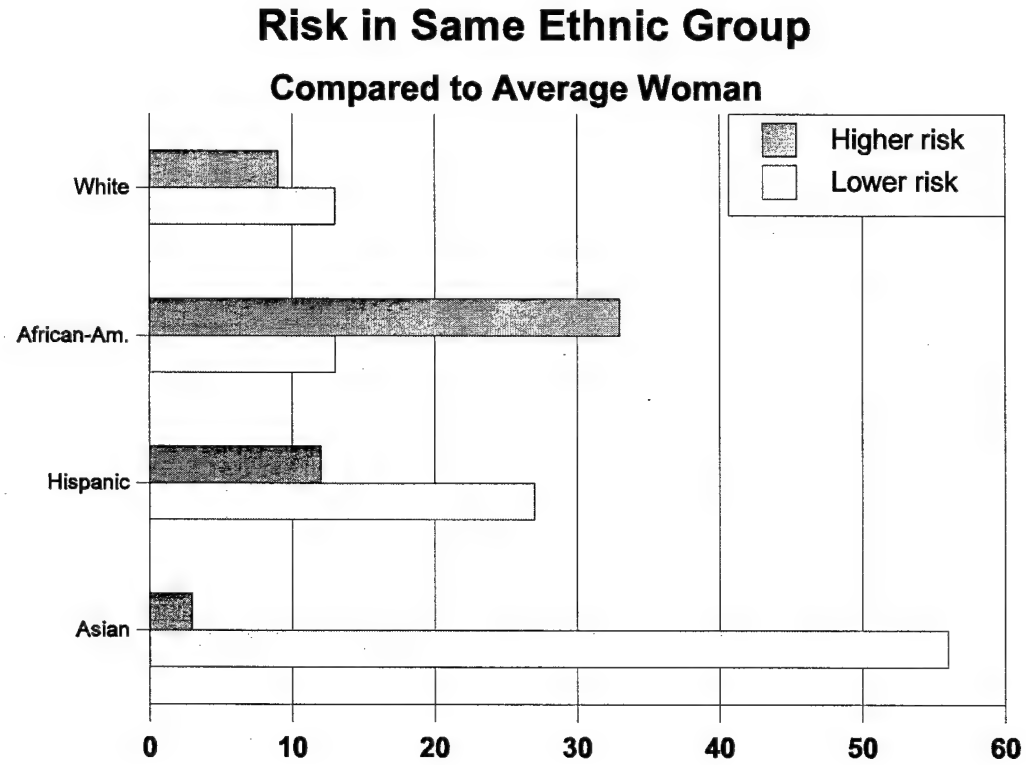
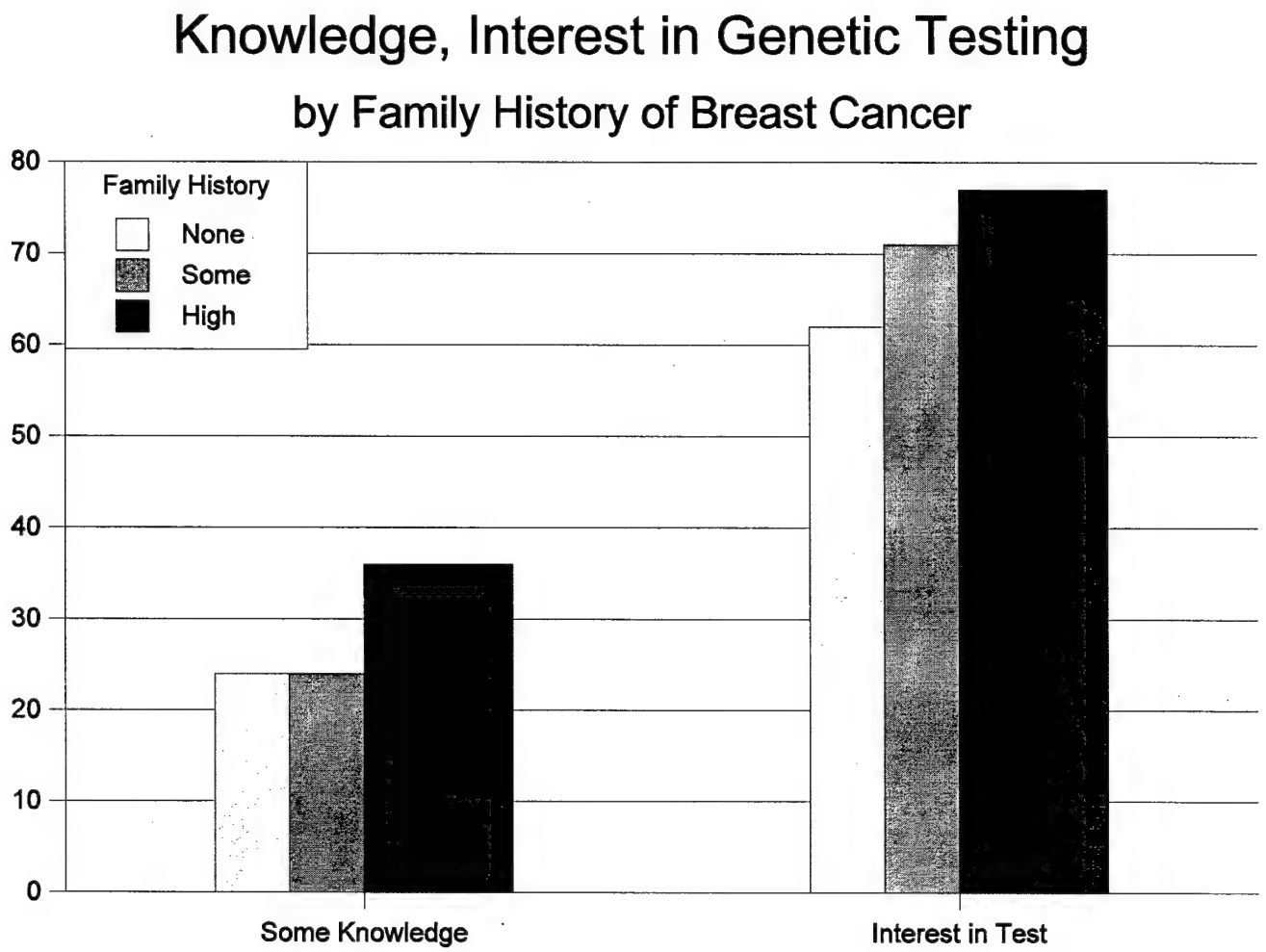


Figure 3. Percent of Women Reporting At Least Some Knowledge of Genetic Testing and Interest in Being Tested by Extent of Family History



APPENDIX D

Educational Interventions for Women Interested in Genetic Testing For Inherited Susceptibility to Breast and Ovarian Cancer

FOCUS GROUP AGENDA

I. Introduction and Explanation of Focus Group Process

Greet participants, have them sign in with their names and addresses on a 4x6 card. Cards will serve as a record of attendance. Names and addresses will facilitate mailing checks.

Introduce moderators, purpose of the focus group, and what tasks will be accomplished. Moderator: Emphasize that in this session we are not looking for "RIGHT" or "WRONG" answers, because there are no right or wrong answers. Emphasize that what is most important is what you really think:

> "Say the way it is for you. Please remember that people see things differently and it is fine if someone says something different than you or if you think about something in another way. All ideas and points of view are welcomed and respected. No put downs here".

Ask if there are any questions.

Voluntary and confidential. Inform women that they can discontinue their participation at any time. Explain the reason for recording, ask that everyone use only first names, assure the participants that no one's name will appear in any publication, report or medical record. Information is for research purposes; it will be kept confidential, and will not be shared with physicians or other Kaiser Permanente personnel.

Any questions?

II. Introduction of Group

Moderator introduces herself, and asks each person to say her first name and tell the group something about herself, such as why she decided to attend the session.

III. Introduction of Topic

Moderator: Today, we are going to be talking about breast cancer, families, and testing for breast cancer genes. It can be difficult to talk about these things, but it is important to learn what women think about these things so that we can educate and help women with the information they want and need.

Let's begin our discussion by talking about breast cancer.

1. **"How much is breast cancer on your mind?"** Those of you who don't think about it much, why is that?

2. **Speaking of families, if your grandmother and one of your aunts had had breast cancer, do you think you would know about it? How much do you know about your family's history of breast cancer? Would this information be discussed and shared in your family?**

3. **"Compared to other women, do you think your chances of getting breast cancer are higher or lower than average? " Why?** What kind of things have you done or not done because you believed

your chances were higher or lower than average?

IV. Explanation and Discussion of Inherited Susceptibility to Breast Cancer
Moderator: Now I'm going to tell you a little more about genes and about breast cancer in families, and then ask for your opinions about some of the issues.

Humans have lots of genes. There are genes for hair color, skin color, and almost all the physical features we are born with. Genes are passed from parents to children, generation after generation, which is the reason that family members may share certain features such as curly hair, or long fingers, or a nose that has a certain shape, which make them look like members of the same family.

There are some diseases which run in families, too. In the same way that a large nose or small feet might be passed from parent to child, so can the tendency to develop a disease. In a small number of cases, breast cancer can be one of these diseases.

[Use family tree picture here]

Let me show you a picture that may help explain what I am talking about. This is an example of a woman's family tree. This picture shows 3 generations of this family. In this family, the grandmother has had breast cancer, and 2 of her daughters have had breast cancer – the sisters of this woman's father. Even though men very rarely get breast cancer themselves, they can pass the genes on to their daughters who can get breast cancer, as you can see in this example. The tendency to develop breast cancer in this family is passed from generation to generation. This is what we mean by having a family history of breast cancer. Even in this kind of family, however, not everyone will have the genes and not everyone will get breast cancer.

Most cases of breast cancer are caused by other factors, most of which we do not know. Only a small number of cases of breast cancer are caused by these genes, which only occur in some families.

Does anyone have questions about the information? (If participants have questions about their personal situation or family history, gently tell them you cannot answer these sorts of questions. You can only clarify the information that was presented. Ask them to write down their questions and you will refer them to someone who can answer their questions at the end of the group).

4. In the information I just told you, did you hear anything completely new that you hadn't heard before? Did you hear anything that shocked or upset you?

5. If your mother and your aunt both had breast cancer, would you feel like your chances of getting breast cancer were high?

6. Would you want to know if cancer in your family was caused by genes? Why or why not? If your family had genes that caused cancer in the family, would you want to keep the information private from people outside your family? Why?

V. Genetic Testing for Inherited Susceptibility to Breast Cancer
Moderator: "Now I'm going to tell you a little about a test for the genes that cause breast cancer, what

the test means, and then discuss some of the advantages and disadvantages of being tested.

There is a blood test that can be used to look for the genes that cause breast cancer in some families. If several members of a family have had breast cancer, it is possible to use this test to see if certain genes are causing breast cancer in the family, and to see who in the family has the gene. Before a woman can take the blood test, she must meet with a genetic counselor who explains the test and the advantages and disadvantages. If a woman then decides to take the test, the result can be positive or negative.

If the blood test is positive and a woman **does have** the genes, it tells her that her chances of getting breast cancer are pretty high, but it cannot tell her for sure that she will get breast cancer. A positive test means that other members of her family probably have the gene, too, and that it is possible for her to pass on the gene to her children. If a woman has already had breast cancer, a positive test may explain why she got breast cancer, and it can tell her that her chances of getting breast cancer in her other breast are pretty high.

If the test is negative – a woman has **not** inherited the gene - it can tell her that her chances of getting breast cancer are average – the same as other women her age and with similar background. A negative test cannot guarantee a woman that she will not get breast cancer because other things besides these genes cause cancer. Does anyone have any questions?

If the test is positive, there is no way to change the gene, but there are some things that a woman with a positive test can do, such as increase her efforts to detect breast cancer early by having more frequent mammograms, having breast examinations by a doctor, and examining her own breasts.

7. Of course we are not offering any testing as part of this project, but do you think you would you be interested in taking this test, based on what you know right now? Why or why not.

8. In your opinion, what would be the advantages and disadvantages in taking the blood test for breast cancer genes?

[Moderator makes separate lists on large sheets of white paper.]

(If it hasn't come up: You could reduce your risk of getting breast cancer by having surgery to remove your breasts.)

9. Should family members discuss being tested with the rest of the family, or should it be a private decision for each family member? Do you think that all members of a family should decide the same way, that is, all members decide to have the test or all members decide not to have it? What might happen if family members disagree about taking the test?

[10. What do you think about genetic testing for a young woman or girl? How do you think the knowledge that she has a high chance of getting breast cancer would change her life?]

11. If you had a positive test, what, if anything would you do? What's the first thing that comes to mind? **What, if anything, would you do if you had a negative test?** What's the first thing that comes

to mind?

12. What do you think about a woman with a positive test who decides to have her breasts surgically removed to prevent breast cancer?

13. Do you think a woman should do things to try to reduce her risk of cancer, or should it be left up to fate or to God?

VI. Consequences and Implications of Genetic Testing for Breast Cancer

Let's talk a little bit about how the test might affect different people.

14. Would you worry about employers or health insurance companies knowing the results if you were interested in taking this test? Would it change your mind about the test?

VI. Kaiser Permanente and Genetic Testing

Moderator: Let's switch a little and talk about genetic testing in Kaiser Permanente.

15. How would you prefer to learn about genetic testing and breast cancer genes? Would you come to class or a group discussion? Would you want to bring family members with you? Would you prefer a video to take home that you could watch by yourself or with other members of your family? Should Kaiser send something to read in the mail or have brochures in the waiting room?

VII. Closing the Group

Ask if there are any final questions. Thank everyone for their participation.